

Application No. 09/888,959

Reply to Office Action dated November 18, 2003

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the following remarks. As an initial matter Applicants wish to thank Examiner Holleran for her time and comments during the teleconferences of January 29, 2004 and February 25, 2004. During these calls, art rejections were discussed and the Examiner's helpful suggestions regarding the same are incorporated herein. In particular, one embodiment regarding the number of CD antigens. Claims 1-3 and 7-20 are currently pending, and claims 1-3, 7 and 18-21 are under consideration. By this amendment, claim 1 has been amended, claim 3 has been canceled and claim 21 has been added to more clearly recite certain aspects of the claimed subject matter. Support for the amendment may be found throughout the claims and specification as originally filed. Support for molecules immobilized to a solid support is provided, e.g., on page 5, lines 17-18. In addition, specific support for antigen binding fragments is provided, e.g., on page 33, lines 10-13. Accordingly, it is respectfully submitted that the amendment does not constitute new matter. This amendment is not to be construed as acquiescence to any rejection and is made without prejudice to prosecution of any subject matter modified by the amendment in a related divisional, continuation, or continuation-in-part application.

Rejections Under 35 U.S.C. § 102

Claims 1-3, 7 and 19 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Robbins *et al.*, Blood 82(4):1277-1287, 1993. In particular, the Action alleges that Robbins *et al.* teach a method of contacting samples with pairs of antibodies that are specific for CD antigens and further alleges that Robbins *et al.* teach a method of distinguishing HCL from CLL using CD19 and CD25 antibodies.

Claims 1-3, 7, 18 and 19 stand similarly rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Valet *et al.*, Cytometry 20:275-288, 1997. Specifically, the Action asserts that Valet *et al.* teach detecting CD10, CD19, and CD23 and thus anticipates the presently claimed invention.

Claims 1-3, 7 and 19 stand rejected under 35 U.S.C. § 102(b) as also allegedly being anticipated by Terstappen (U.S. Patent No. 5,234,816). In particular, the Action alleges

Application No. 09/888,959

Reply to Office Action dated November 18, 2003

that Terstappen discloses a method for classifying leukemias comprising contacting samples with antibodies that bind to CD antigens.

In addition, claims 1-3, 7 and 19 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Moreau *et al.*, Am. J. Clin. Pathol. 108:378-382, 1997, Matutes *et al.*, Blood 83(6):1558-1562, 1994, or Kurec *et al.*, British J. Haematology 81:45-51, 1992. More specifically, the Action alleges that Moreau teaches a method for diagnosing CLL based upon a binding pattern to a panel of antibodies; Matutes allegedly teaches a method to distinguish splenic lymphoma from villous lymphocytes from CLL or HCL that includes antibody binding; and Kurec allegedly teaches immunophenotypic classification of CLL.

Applicants respectfully traverse these related bases of rejection and submit that none of the cited references anticipate the claimed invention. Applicants note that claim 1 has been amended, without acquiescence to these bases of rejection, to explicitly recite that the arrayed immunoglobulin molecules are immobilized to a solid support. Since none of the cited references describe methods using an immobilized support, they clearly do not teach this feature of the claimed invention and, therefore, cannot anticipate the instant claims. Applicants respectfully request that Examiner reconsider and withdraw these bases of rejection in light of this amendment.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over either Robbins *et al.*, Blood 82(4):1277-1287, 1993 or Valet in view of Chang (U.S. Pat. No. 4,591,570).

Claims 1-3, 7, 18 and 19 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Robbins, Terstappen, Moreau, Matutes, or Kurec, in view of Chang.

Applicants respectfully traverse these bases of rejection and submit that the Examiner has not established a *prima facie* case of obviousness over either combination of references. Applicants note that claim 1, as presently amended, recited the feature that the arrayed immunoglobulin molecules are immobilized to a solid support. However, none of the cited references teach or suggest the use of an immobilized support. Accordingly, the cited

Application No. 09/888,959

Reply to Office Action dated November 18, 2003

references, alone or combined, do not teach or suggest each element of the claimed invention, as clearly required to establish a *prima facie* case of obviousness. *In re Royka*, 490 F.2d 981 (CCPA 1974).

In addition, Applicants submit that even assuming *arguendo* that each element of the claimed invention was taught by a cited reference, the cited combinations of references would fail to render the claimed invention obvious, since the references fail to provide the requisite teaching or suggestion of the desirability of combining or modifying the teachings of the references to reach the present invention. Applicants respectfully submit that the mere fact that the teachings of the prior art *can* be combined or modified, or that a person having ordinary skill in the art is *capable* of combining or modifying the teachings of the prior art, does not make the resultant combination *prima facie* obvious, as the prior art must also suggest the desirability of the combination or modification (*see, e.g., In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990); *In re Fritch*, 23 USPQ2d 1780 (Fed. Cir. 1992)). Since none of the cited references teach or suggest any advantage or desirability of modifying the teachings of the references to develop a method wherein immunoglobulin molecules are immobilized to a solid support, Applicants submit that the Action fails to establish a *prima facie* case of obviousness. Applicants further note that the teaching or suggestion to make a claimed combination must be found in the prior art and not based upon the Applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed Cir. 1991). Accordingly, a rejection of the instant claims would appear to rest upon impermissible hindsight based upon the instant application's description of methods of identifying a type of leukaemia comprising contacting a sample with an array of immunoglobulin molecules immobilized to a solid support.

Applicants further submit that the nonobviousness of the claimed invention is evidenced by secondary factors clearly demonstrating the superiority of the present invention as compared to previously known methods. Specifically, Applicants note that the present invention has been licensed, as demonstrated by the fact that the claimed invention has been licensed to a medical diagnostic company to fulfill a commercial need, as described in paragraph 8 of the accompanying Declaration of Richard Ian Christopherson, Ph.D. In addition, the Declaration provides evidence of the superiority of the presently claimed invention over previously described

Application No. 09/888,959

Reply to Office Action dated November 18, 2003

methods, including flow cytometry-based methods, as described in the cited references, including increased rapidity, greater cost effectiveness (paragraphs 5 and 6), and increased accuracy and efficiency (paragraph 7). Applicants submit that this objective evidence clearly demonstrates the non-obvious nature of the presently claimed invention. Accordingly, Applicants submit that even assuming *arguendo* that a *prima facie* case of obviousness was established, this evidence would be sufficient to rebut the same.

Applicants respectfully request that the Examiner reconsider and withdraw these bases of rejection in light of the above amendment and remarks, and the accompanying Declaration providing objective evidence of the non-obvious nature of the invention.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 3 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in the recitation of a list of CD antigens. Specifically, the Examiner alleges that the list includes elements that are not CD antigens.

Applicants note that claim 3 has been canceled, without acquiescence to this basis of rejection, thereby obviating this basis of rejection. Therefore, Applicants request that this basis of rejection be withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claim 3 stands rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to satisfy the written description requirement. More specifically, the Examiner asserts that the previous amendment to claim 3 introduced new matter into the specification. In particular, the Examiner states that the amendment to claim 3 added elements to a list of CD antigens, but the specification did not describe an array containing the antigens listed in amended claim 3.

Applicants respectfully traverse this basis of rejection. Applicants note that claim 3 has been canceled, without acquiescence to this basis of rejection, thereby obviating this rejection. Nevertheless, Applicants submit that specific written description support is provided

Application No. 09/888,959

Reply to Office Action dated November 18, 2003

for these elements in the specification as originally filed, including, *e.g.*, on page 44, lines 24-30.

Applicants respectfully request that the Examiner withdraw this rejection.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all of the claims remaining in the application are allowable. Favorable consideration and a Notice of Allowance are earnestly solicited. Should any issues remain, the Examiner is urged to contact the undersigned at (206) 622-4900.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



William T. Christiansen, Ph.D.

Registration No. 44,614

WTC:jto

Enclosure:

Declaration of Richard Ian Christopherson

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

V462371_1.DOC